

REMARKS

Claim 21 has been amended to address indefiniteness problems and define the invention more precisely. Claim 11 has been canceled and new claim 22 has been added.

Before specifically responding to the above referenced objections, applicants provide the following information regarding the present invention for clarification. In general, the invention, described by the above claims, uses formal linkages to chain extend certain monomer units within the backbone of a chain diol prepolymer in order to create hydrolyzable links within said backbone. This is a specific polymeric architecture designed to produce a chained, diol prepolymer that is readily hydrolyzable. The specific formula and limitations set forth in the presently amended claims allow a user to select a certain number of monomer units, and, therefore, a certain number of formal linkages within the backbone of the prepolymer, in order to adjust the level of hydrolyzability of the prepolymer.

Further, regarding the specific limitations of the presently amended claims, claim 21 sets forth the specific architecture described above with the following further limitations. First, the monomer units are carbon or carbon or heteroatom chains. In order to be a chain, one must have, at a minimum, two atoms, and, thus, the monomer unit cannot be CH₃. This is not a change from previous configurations of the claims because the claims always called for "R" to be carbon atoms (plural) or carbon, nitrogen, or oxygen atoms (plural). Also, while the examiner has objected to the use of the term "chain" during the prosecution of this application (and applicants have attempted to draft claims using a description of what "chain" means to one skilled in the art rather than using the specific term as a result), because of the new matter issues raised in this Action, applicants have reverted to using this term in the claims (since this is the term used throughout the specification). To address any future objections to the use of this term, applicants

note that a simple search of the USPTO database for patents from 1976 to the present for the term "carbon chain" within claims results in over 1700 hits. Almost every one of these issued patents appears to use the term in exactly the same manner as applicants' use the term in the present application (carbon atoms bonded to one another). Therefore, it appears clear that the term "chain" is understood by those skilled in the art and, as such, perfectly proper to use in patent claim language (as has been done in well over 1700 issued patents).

The second limitation that applicants wish to call to the attention of the examiner is that n is equal to 2-10. By definition, this means that the prepolymer of the present invention is chain extended by 2 to 10 formal linkages and contains 2 to 10 monomer units.

A third limitation is that the monomer units have a molecular weight of 300-1000. This greatly reduces the potential scope of the carbon or carbon/heteroatom chains that may be employed in the present invention.

Fourth, the formal linkages in the backbone are hydrolyzable moieties that hydrolyze in a 2N acid at room temperature. This limitation further limits the monomer units available in the present invention by precluding monomer units having linkages that would preclude the formal linkages within the backbone from being hydrolyzable. The specifics of such limitations were discussed at length in a previous submission, including a declaration by one of the applicants.

Fifth, regarding the dependent claims, claim 22 indicates that five to eight formal linkages appear within the backbone of the prepolymer. By definition, this limits the number of repeating monomer units (" n ") used. Claim 10 provides a specific prepolymer, specifying the molecular weight of the monomer unit (500), the actual make-up of the monomer unit (a polycaprolactone chain), and the number of monomer units used (which also gives the number of

formal linkages within the backbone of the prepolymer) via the molecular weight of the prepolymer (this can easily be calculated by one skilled in the art).

In providing the above information regarding the limitations of the presently amended claims, applicants believe that the differences between the present invention and the numerous general references cited by the examiner should now be clear. The examiner sets forth references that merely disclose general, well-known polymeric structures that might contain oxymethylene or formal group(s). Nothing in any of these references discloses the specific, unique prepolymer architecture, with the specific limitations found within the present claims.

Finally, the inherency argument made by the examiner in relation to formal linkages within prior art polymers in no way withstands technical scrutiny. Applicants have provided a sworn statement by a polymer chemist with over forty years of practical experience that many polymeric structures exist that contain formal linkages, but such polymeric structures are not hydrolyzable. The sworn statement provides technical rationale as to why such structures are not hydrolyzable. Even if the examiner disregards the technical veracity of the rationale as to why such polymers are not hydrolyzable, one of the specific examples was developed, tested, and patented by the expert making the sworn statement and specifically found not to be hydrolyzable. Thus, applicants assert that no further rationale exists to argue that formal groups within polymers are inherently hydrolyzable.

Regarding the specific current rejections, claims 11 and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as being obvious over each of Brachert et al. and Finck et al. In support of these rejections, the examiner indicates that the references disclose polymers that may include polyformals groups and/or polyoxymethylene groups.

As described above, the examiner's assumption that the claims would allow "R" to be CH₃ is incorrect. Both the past claims and the present claims require, at a minimum, a chain of two carbon atoms or a carbon and heteroatom chain. Regardless, the mere mention that a polymer contains polyoxymethylene groups or polyformals in no way discloses the limitations of the claims (as discussed above). These references do not disclose the prepolymer architecture described by the present claims, including a diol prepolymer that is chain extended by hydrolyzable formal linkages. Therefore, the references do not anticipate the present claims. Further, since the limitations are not found in the references, no combination of the references could ever result in the present invention. Also, nothing in the references would lead one skilled in the art to attempt to modify the standard polymers set forth in the references to obtain the unique prepolymer architecture of the present invention. No impetus exists for any such modification because these references do not deal with hydrolyzability, nor do they state or imply that formal linkages within the unique architecture of the present invention are hydrolyzable. Therefore, the references, by themselves or in combination, in no way make the present invention obvious.

Claims 11, 12, and 21 stand rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative under 35 U.S.C. § 103(a) as being obvious over each of Barnes et al., Hostettler, Genz et al., and Okita et al. First, applicants assume that this rejection relates to claims 10, 11, and 21, since claim 12 has been previously canceled. Regarding the substance of the rejection, the only argument set forth by the examiner relates to inherency. Applicants believe that the above discussion of this subject obviates any such argument. Applicants also humbly repeat their request that any future argument related to this issue actually address the significant amount of

discussion and information provided by applicants in response to numerous rejections of an identical nature.

Claims 10, 11, and 21 stand rejected under 35 U.S.C. § 103(a), as being unpatentable over Emmerling et al., in view of Hostetter et al., Okita et al., and Genz et al. As discussed above, none of the polymers disclosed within these references discloses the unique architecture of the present invention. For the examiner's information, polyformal polymers are not the same as a chain extended diol prepolymer using a formal linkage. They do not comprise the same type of structure, and, therefore, do not comprise the same properties. Also, a mere reference that a caprolactone group is found within a hydroxy terminated polymer in no way discloses using a polycaprolactone chain within the unique architecture described by the present claims. If, after these remarks, the examiner has any questions regarding the differences between the structures disclosed in the prior art and the unique architecture employed in the present invention, applicants' representative would be happy to provide a non-inventor, polymer expert to meet with the examiner in person to describe the differences in the structures in more detail.

Regarding the obviousness rejections, due to the structural differences in the prior art polymers compared to the present invention, it would not be technically reasonable nor, likely, possible, to combine the reference constituents as the examiner suggests. Also, again, none of the cited references discuss, disclose or deal with the hydrolyzability issue in any manner, and, therefore, applicants argue that there would be no reason or impetus to combine or modify the references to obtain the present invention as the examiner suggests. Applicants, again, humbly request that any future arguments related to combining references for an obviousness rejection provide some impetus for such a combination beyond "it would be obvious for one skilled in the art to do so."

Claims 10, 11, and 21 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Specifically, the examiner objects to the definition of R within claim 21 and the last three lines of the claim. The examiner also objects to the functionality language of claim 11 and the potential inconsistencies between claims 21, 10, and 11. Applicants have amended claim 21 to clarify the invention and address potential indefinite language. The definition of R is now clear. R is carbon or carbon/heteroatom chain monomer unit, having a molecular weight between about 300 and 1000. As discussed above, these terms are well known in the art and, also, these terms have been used within the claims of many issued patents (thereby showing the validity of using said terms). R is not only limited by the composition and molecular weight limitations set forth above, but also by the limitation that the formal linkages (that are chain extending the monomer units via the formula) are hydrolyzable moieties. As described in previous submissions, many specific types of structures and linkages could result in the formal linkages, even within the unique architecture of the present invention, not being hydrolyzable.

The value of "n" is defined as being a number from 2 to 10. This further defines the structure as having 2 to 10 monomer units chain extended by 2 to 10 formal linkages. Also, the examiner questions the terminology indicating the hydrolyzable formal linkage(s) are in the backbone of the prepolymer. While applicants believe that the use of "the" is proper from an antecedent basis due to the above formula (clearly showing that the formal linkages will be in the backbone of the prepolymer), applicants have amended the language to dispel any confusion. Further, as described above, R cannot be oxymethylene as the examiner suggests, therefore, based upon the formula within the claims, the formal linkages must be in the backbone of the prepolymer.

The claims have also been amended to remove the somewhat confusing "consisting essentially of" language as well as the language related to the acid concentration. Regarding the functionality issue, applicants have canceled claim 11, making the issue moot. However, for the examiner's information, a whole number functionality for a polymer is normally only theoretical in nature. When preparing a polymer, one can almost never obtain a 100 percent yield of the exact polymeric structure one is attempting to make. Spurious offshoots from portions of the polymeric structure almost always occur. This small percentage of "imperfect" structures will make the actual functionality of the overall polymer (which is computed as an average of the functionality of the true polymer yield) vary from the theoretical value. However, to remove confusion, applicant has canceled the claim at issue.

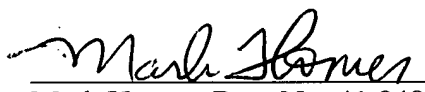
Regarding the dependent claims, the amended claim 10 and the new claim 22 further define the specific structure of the invention. Claim 22 includes the limitation that the prepolymer has five to eight formal linkages within the backbone of the prepolymer. By definition, this means that $n=5-8$, and, therefore, there are five to eight monomer units that are chain extended by the formal linkages. Claim 10 has been amended to provide an exact prepolymer embodiment of the present invention. A polycaprolactone group, having a molecular weight of 500 (allowing the calculation of the exact group) is the monomer unit and it is chain extended by formal linkages in a quantity to give a prepolymer having a molecular weight of about 3600 (this allows one skilled in the art to calculate the exact number for "n", and, therefore, the exact prepolymer).

Finally, claims 10, 11, and 21 stand rejected under 35 U.S.C. § 112, first paragraph as including new matter, and, thereby, failing to comply with the written description requirement. Applicants have amended the claims to remove all language which the examiner has indicated

relates to new matter. All of the language and terms found in the amended claims can now be found directly within the present specification. Therefore, this issue should now be moot.

Accordingly, applicant believes that claims 10, 21, and 22 are in condition for allowance and respectfully requests the examiner to withdraw all objections and rejections and allow said claims. Should the examiner need more information regarding this matter or have further suggestions regarding this application, feel free to call the undersigned at 301-744-5603.

Respectfully submitted,


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